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April 2, 2003

ASSOCIATION

Dockets Management Branch (HFA-305) Food and Drug Administration 5600 Fishers Lane, Room 1601 Rockville, Maryland 20852

Re:

Docket No. 02N-0276 -- Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Proposed Regulation Published February 3, 2003, 68 Federal Register 5378)

Dear Sirs:

These comments are submitted by the American Wholesale Marketers Association ("AWMA"), the only international trade association working on behalf of convenience distributors in the United States. Our distributor members represent more than \$45 billion in U.S. convenience product sales annually. Associate members include manufacturers, brokers, retailers and others allied to the convenience product industry. Our comments focus on the impact of the proposed regulations on AWMA's distributor member companies, nearly all of whom expect to register with the Food and Drug Administration ("FDA") pursuant to the Bioterrorism Act and the regulations promulgated thereunder.

The AWMA recognizes the need to safeguard food security, and our industry is committed to promoting the safety of our food supply to ensure the health and well-being of all Americans. The proposed regulations reflect the efforts by the agency to consider industry issues and concerns that were raised in informal comments last year. AWMA commends FDA for this initiative, and we have only a few additional comments. Unless otherwise indicated, references are to the sections of the proposed amendments to Title 21, Code of Federal Regulations.

Proposed Sec. 1.231(b) would afford the opportunity for companies to register by mail. It is very important that this method be given adequate resources and planning, because this will be the only method available to a number of AWMA member companies. The preamble to the regulation implies that the agency will have a strong preference for electronic registration and may discourage mail-in registration. This could be unfair to small companies and remotely-located facilities. There is nothing wrong with the text in this section of the proposed regulation, but, if the mail-in registration system is not adequately supported, the implementation could be a significant burden for companies without the computer resources which are necessary for electronic registration.

Proposed Sec. 1.232(e) would require the registrant to list the food product categories it handles, using the FDA definitions contained in 21 CFR Sec. 170.3. However, many of the companies which would be subject to this registration requirement have not had any contact with FDA in the past, and they are not familiar with the agency's regulatory scheme. There are bound to be mistakes in the reporting of food categories, and newly-registered companies should not be

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subject to regulatory action for mistakes. Mistakes may arise for any of the following reasons:

- -- A company's product classification scheme uses different definitions than the FDA scheme.
 - -- The individual preparing the registration may accidentally enter the wrong categories.
- -- Additions of product categories at some facilities may not be properly reported and updated to a central management office.

Pursuant to proposed Sec. 1.241(a), failure to register would be a prohibited act (21 USC Sec. 331) and subject to criminal penalties (21 USC Sec. 333). However, it is not clear from the proposed regulations what the ramifications are from an error or omission in a registration submission or an update. If the same penalties were to apply, the potential consequences are grossly inconsistent with the actions involved in registration. FDA should adopt a policy not to bring regulatory actions against companies which make errors in registration. We recommend an explicit policy that FDA will not seize or enjoin the distribution of any food products of a company which has registered, even if there are significant errors in the registration, nor should such companies be subject to criminal charges.

<u>Proposed Sec. 1.234(a)</u> would require a registrant to update registration information within 30 calendar days of a change. The proposal raises two different questions:

- -- Although the proposed regulation says the update is required for "any change to any information previously submitted," the examples given in the same sentence all relate to facility management. Is a company required to file an update to report a change in the categories of food which are carried?
- -- We recommend that the agency reconsider the within-30-days-of-change reporting requirement. If a change in food categories is subject to the update report, FDA is going to be inundated with minor changes, and the registrants will be preparing updates on a nearly constant basis. If updates are only required for the management changes identified in the proposed regulation (i.e., name of owner, operator, or agent in charge of the facility), it will still be possible for FDA to communicate with the facility even if the agency does not have the most current name. As an alternative, AWMA recommends a semi-annual update, on a set schedule, which would report all changes during the previous six months; if there are no changes, no update would be required. FDA could establish a staggered reporting schedule, so the updates are spread out over the year. Such changes in the update schedule would have very little effect on the agency's ability to trace the distribution of a food product, but they would greatly reduce the reporting burden on the registrant.

Simplifying reporting is very important to the wholesale distributor industry. Most of our distributor members are small companies, but they carry a large number of items in inventory, and, of course, the mix of items changes seasonally. Since food products constitute a significant

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responsibilities could be a substantial burden.

Finally, the agency's estimates of the time involved in the research and document preparation required to register (Table 10, 68 Fed. Reg. at 5394) are extremely low for our industry. For instance, FDA predicts that it will take an administrative worker only 0.75 hours to fill out the registration form. Even if this is true, the estimate does recognize that he or she will likely spend several hours on internal research to identify the information that is required to be reported. This time will be spent in gathering the information on key contact persons and assessing the categories of food product inventory. The time burden is not going to be much less for an update. The anecdotal responses of our members consistently support the conclusion that far more time will be required. The regulatory burden will be significant, and we urge FDA to strive to reduce the requirements at every opportunity.

Thank you for the opportunity to comment on these proposed regulations.

Respectfully submitted,

Scott Ramminger, President

American Wholesale Marketers Association